

**REMARKS**

Claims 1, 3-4, and 10-13 are currently pending in the present application. By virtue of this response, claim 1 has been amended. No claims have been cancelled or added. No new matter has been added. Accordingly, claims 1, 3-4, and 10-13 remain under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Applicants wish to thank the Examiner for withdrawal of the rejection of claims 1, 3-4, and 10-13 under 35 U.S.C. § 103 (a) to Meert et al.

***Claim Rejections Under 35 USC § 103***

Claims 1, 3-4, and 10-13 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. 5,910,512 to Conant. Specifically, the final Office Action states that Conant does not teach the claimed kit having separate components, but that it would have been obvious for one of ordinary skill in the art at the time the instant invention was made to pack capsaicin and the solvent or the carrier for capsaicin separately and mix them before application to the skin because Conant teaches suspending water soluble capsaicin in various hydrophilic bases before application to the skin for treating pain. Further, in response to Applicant's arguments (filed in the response dated September 9, 2006) that the instant claims require the second composition to be a separate component, the Examiner states that in one embodiment of the specification, the two components are present together, and the instant claims as presented read on this embodiment. The Examiner also argues that the recitation of "for cleansing" in the claims with respect to the second composition is language of intended use that does not carry any patentable weight.

Applicants respectfully disagree that any variation that describes a capsaicin-containing composition (first composition) and a cleansing composition (second composition) as present together in a single formulation is present in the specification, and request that the Examiner specifically cite to that portion of the text at which it may be found. Also, with respect to the Examiner's argument that the recitation of "for cleansing" does not carry any patentable weight, Applicants point out that although the claimed invention differs from Conant in that it includes a

composition that cleanses, it is primarily distinguished from Conant because it has a second composition that is *separate* from a first capsaicin-containing composition.

Additionally, Applicants again disagree that the teachings of Conant set forth a *prima facie* case of obviousness. In order to set forth a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine teachings. Second, there must be a reasonable expectation of success. Lastly, the prior art reference (or references when combined) must teach or suggest all claim limitations. *See* MPEP §2143.

Motivation to modify Conant. Applicants assert that no motivation exists in Conant to make a kit, having as *separate* components, a *first composition* having capsaicin or a capsaicin analog for application to a bodily surface, and a *second composition for cleansing* the bodily surface, as required by claims 1, 3-4, and 10-13. First, no motivation exists because Conant is only concerned with delivery of capsaicin into the skin for pain relief, not capsaicin removal to reduce or eliminate pungency and irritation of any residual capsaicin that is left on the skin, as described by the Applicants in paragraphs 14, 16, 17, and 50, among other places, of the present specification. A very significant problem associated with capsaicin-containing formulations is pungency and environmental/patient contamination (e.g., spread to other body parts, clothes, bedding, etc.) that is caused by residual capsaicin on the skin. This problem, which is intrinsic to the administration of topical capsaicin, relates to the objective of having a composition for effectively removing residual capsaicin left on the skin after topical application. There is no mention by Conant of any formulations for capsaicin removal or the need for it. Thus, Applicants contend that no motivation exists for Conant to modify his invention to include a second, separate composition for removing capsaicin from the skin.

Furthermore, no motivation exists in Conant to make a kit, having as *separate* components, a *first composition* having capsaicin or a capsaicin analog for application to a bodily surface, and a *second composition for cleansing* the bodily surface because the cited reference

attempts to solve the problem of burning or stinging due to incorporation of *strong solvents* at the site of topical application. Thus, instead of using harsh solvents such as alcohol, chloroform or ether, Conant describes formulations that include various red algae extracts as a base. Thus, Applicants submit that any motivation or suggestion to modify Conant to include a second cleansing composition for capsaicin removal from the skin does not exist.

Reasonable expectation of success. A reference may be modified to reject claims as being *prima facie* obvious as long as there is a reasonable expectation of success of making the claimed invention. However, the mere fact that references can be combined or modified does not render the modification or resultant combination obvious unless the prior art also suggests the desirability of the modification or combination (*See*, MPEP §2143.01). As discussed above, there is no motivation or suggestion in Conant to include a second cleansing composition for removal of capsaicin from the skin.

Teach or suggest all claim limitations. In order to establish a *prima facie* case of obviousness, all claim limitations must be taught or suggested by Conant. Again, Conant does not teach or suggest a second cleansing composition for removing capsaicin from the skin. Accordingly, Applicants submit that the kit recited in claims 1, 3-4, and 10-13 is nonobvious.

However, to reflect the arguments provided above, and in order to expedite prosecution, Applicants have amended claim 1 to emphasize that the first and second compositions are separately packaged, which is not described by Conant. Support for this amendment is found, among other places, at page 1, paragraph 4; page 16, paragraph 43; and page 17, paragraph 44. Additionally, Applicants have amended claim 1 to recite that the second composition *removes* capsaicin from a bodily surface *after application* of the first composition to further clarify that the first composition is separate from, and not mixed with, the second composition prior to application. Conant does not describe any composition that is applied to the skin after application of the capsaicin-containing formulation, or any composition that removes capsaicin from the skin, as required by amended claim 1. Thus, because Conant does not teach or suggest all the limitations of amended claim 1, Applicants submit that the kit recited in claims 1, 3-4, and 10-13 is nonobvious.

Withdrawal of the rejection of claims 1, 3-4, and 10-13 under 35 U.S.C. § 103(a) is respectfully requested.

**CONCLUSION**


In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **524522000500**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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